

### **REMARKS**

Prior to the present amendment, claims 11 and 36 were pending. By the present amendment, claim 36 was amended. Accordingly, claims 11 and 36 are currently pending. No new matter has been entered by the amendments of the claim.

### **INTERVIEW**

Applicant thanks Examiner Royds for extending the courtesy of a telephone interview with applicant's representatives, the undersigned and Irving N. Feit, on December 14, 2010. The discussion below contains a summary of the interview.

### **35 U.S.C. 112, SECOND PARAGRAPH, REJECTION**

Claims 11 and 36 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. According to the examiner, the claims "fail to set forth the identity of the 'activity' of the 'single component' such that it would have been clear as to what components are included and/or excluded from the instant claims." (Office action page 3, first sentence of the second paragraph.) The examiner further states that "[a]pplicant is urged to clarify the identity of the 'activity' of the 'single active component' as recited in the claims..." (Office action page 4, last sentence of second paragraph.)

During the interview, the term "single active component" was discussed. The examiner maintained that the activity was not clear and that the word "active" was problematic.

Applicant's representative suggested deleting the word "active" from claim 36. The examiner indicated that the deletion of the word "active" would probably overcome the 35 U.S.C. 112, second paragraph, rejection of record.

Applicant has deleted the word "active" from claim 36 in the present amendment. Therefore claim 36 states "the method comprising topically administering a composition

comprising an effective amount of a *single component that reduces cutaneous facial flushing*” (emphasis added).

Reconsideration and withdrawal of the 35 U.S.C. 112, first paragraph, rejection is respectfully requested.

### **35 U.S.C. 103 REJECTION**

The examiner maintained the rejection of claims 11 and 36 under 35 U.S.C. 103(a) as being unpatentable over WO 02/36144 (hereinafter “*Arnold*”) in view of U.S. Patent Publication No. 2003/0229088 (hereinafter “*Gil*”) Wymenga et al., “Management of Hot Flushes in Breast Cancer Patients,” *Acta Oncologia* 41(3):269-275(2002) (hereinafter “*Wymenga*”) and EP 1069124 (hereinafter “*Ito*”).

The examiner states in the office action that the previously filed amendments to the claims would not overcome *Arnold* because “applicant has failed to clearly set forth the ‘activity’ such that it would be clear to one of skill in the art what compounds would be excluded from the instant claims.” (Office action page 5, 1<sup>st</sup> full paragraph.) The examiner further states that *Arnold* “still applies as relevant prior art over the instant claims, absent factual evidence to the contrary and further absent any explanation as to what particular ‘activity’ is intended to be circumscribed by the phrase ‘single active component.’” (Office action page 5, 1<sup>st</sup> full paragraph.)

In order to expedite examination, applicant has deleted the word “active” from the claims so the independent claim is limited to a method involving the administration of a composition containing “a single component that reduces cutaneous facial flushing.” The single component consists of brimonidine tartrate. Accordingly, the composition can only contain one component that reduces the facial flushing. The addition of any other components that reduce facial flushing is excluded by the claim language. See claim 36 reprinted below.

36. (Currently Amended) A method of treating facial flushing associated with menopause-associated hot flashes in a human in need thereof, the method comprising topically administering a composition comprising an effective amount of a single ~~active~~-component that reduces cutaneous facial flushing, wherein the single ~~active~~-component consists of brimonidine tartrate, and a dermatologically acceptable carrier, locally to facial skin of the human, wherein the brimonidine tartrate acts locally to reduce cutaneous facial flushing.

Although the transitional word “comprising” appears after the word “composition,” the composition is limited to “a single component that reduces cutaneous facial flushing, wherein the single component consists of brimonidine tartrate....” Therefore, while the composition may contain other ingredients, *e.g.*, dermatologically acceptable excipients, as a result of the inclusive “comprising” language, the other ingredients in the composition cannot reduce cutaneous facial flushing.

Accordingly, independent claim 36 necessarily excludes the use of compositions containing compounds in addition to brimonidine tartrate that reduce cutaneous facial flushing. Accordingly, the primary reference, *Arnold*, does not render the claims obvious because it requires one or more GnRH analogue compound to treat the side effects of ovariectomy or symptoms associated with menopause. Claim 36 excludes the possibility of one or more GnRH analogue compound being in the claimed composition. Therefore, *Arnold* actually teaches away from the claimed invention.

Applicant believes that the new wording of claim 36 overcomes the 35 U.S.C. 103(a) rejection. If the examiner still has concerns, applicant would welcome a dialog with the examiner regarding the wording of the claim.

In order for a *prima facie* obviousness rejection to be made, the combined teachings of the references must suggest the claimed invention to one of ordinary skill in the art. None of the references cited by the examiner suggest topical treatment of cutaneous facial flushing with the single ingredient of brimonidine tartrate. In fact, the primary reference, *Arnold*, teaches away from the claimed invention. Accordingly, applicant respectfully requests withdrawal of the obviousness rejection.

In view of the clear distinction of the presently amended claim over the primary reference, applicant does not consider it necessary to repeat his assertions of the deficiencies of the secondary references. Applicant refers to his previous response if the examiner wishes to review them.

Applicant respectfully submits that the application is now in proper form for allowance, which action is earnestly solicited. If resolution of any remaining issue is required prior to allowance of the application, it is respectfully requested that the examiner contact applicant's attorney at the telephone number provided below.

Respectfully submitted,

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